



(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
03.07.1996 Bulletin 1996/27

(51) Int. Cl.⁶: **A61F 2/28, A61F 2/30,**
A61L 27/00

(21) Application number: **95119960.3**

(22) Date of filing: **18.12.1995**

(84) Designated Contracting States:
DE FR GB

(30) Priority: **26.12.1994 JP 323202/94**

(71) Applicant: **KYOCERA CORPORATION**
Yamashina-ku, Kyoto-shi, Kyoto (JP)

(72) Inventors:
 • **Toshihiko, Shimotoso**
2101-2 Koshinohara
Shiga 520-23 (JP)

• **Terui, Akira,**
1212 Serikawa-cho
Shiga 522 (JP)
 • **Kitano, Hiroyuki,**
1166-6 Hebimizo-cho
Shiga 527 (JP)

(74) Representative: **Henkel, Feller, Hänzel & Partner**
Möhlstrasse 37
81675 München (DE)

(54) **Living body-supporting member and preparation process thereof**

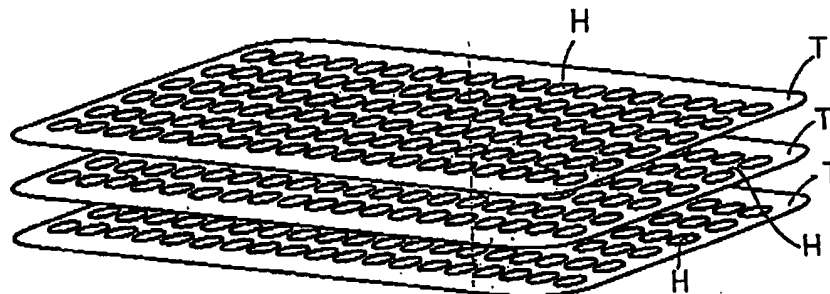
(57) A living body-supporting member having a surface layer with multiple pores regularly arranged therein, in which the porous portions constituting the living body-supporting member are made of ceramics giving no harm to a human body. And a method to perforate multiple pores in a green sheet made of said ceramics, to laminate said green sheets so that pores communicate with each other, and to fire it.

The living body-supporting member is coupled strongly with the bone, and there is no risk that it may

drop out from the supporting portion. Even if the substrate is composed of ceramics, the substrate and the surface layer can be integrally coupled with each other, thereby there is no risk that both of them are separated.

Furthermore, according to the above method, the pore shapes of said porous body can be preliminarily designed so that pores communicate with each other while being displaced for every certain depth, and it can be accurately controlled in the production thereof.

FIG. 1



Description

Background of the Invention

The present invention relates to a living body-supporting member which constitutes an artificial root of tooth and the like used for reconstruction of bone functions and joints of limbs lost due to disease or disaster, or teeth lost due to old age or disease, and the preparation process thereof.

As the above-mentioned artificial supporting member having a porous body, there have been proposed the ones made of metal or ceramic.

As said artificial supporting member made of metal, there have been, for example, an artificial supporting member made of metal which is obtained by sintering and fixing beads made of metal on the surface thereof, the one obtained by forming a porous body on the surface thereof by casting, or the one obtained by laminating lots of meshy sheets.

On the other hand, as the one made of ceramics, there has been proposed a method in which organic materials such as organic resin powders and organic resin fibers are dispersed in the ceramic raw material at the time of preparation of the raw materials, and three-dimensional net-like organic materials are blended into the inside of the mold by firing, and after forming, the organic portion is oxidized and disappeared by dry firing to obtain the porous material.

However, in said conventional art, there have been problems described below.

Namely, any of said conventional art cannot control accurately the shape of pores, other than the one which laminates lots of meshy sheets, therefore the pore shapes may be different for every product, or they cannot optimally lead the bone to reproduce and penetrate.

On the other hand, said mesh sheet multilayer type can accurately control the pore shape so that it can lead optionally the bone to reproduce and penetrate, but since it is composed of metal, there is a problem in the integration with the ceramic materials. Therefore, there have been such problems that the bone drops out from the ceramic substrates, or even if it does not drop out therefrom, the micro-movement due to the slackness between substrates gives bad influence to the living body, or it may affect the abrasiveness of the sliding face.

The present invention which solves the above problems is to make the porous body constituting the living body-supporting member with ceramics giving no harm to the living body and form multiple pores communicating with each other while being displaced for every certain depth.

And as a method to obtain such porous body, the lamination technique of the ceramic package is applied. Namely, there is provided a method in which multiple pores are perforated in a green sheet of said ceramic material, and said green sheet is optionally laminated so that pores communicate with each other, then it is fired.

By laminating and integrally sintering the unfired ceramic thin plate in which multiple pores or slits are perforated, while displacing the position of pores perforated in the thin plate for every roughly certain depth, the porous body can be obtained in which the micro pores communicate three-dimensionally, and the circulation state of the micro pores is properly controlled. This porous body becomes directly the living body-supporting member, or it may be coupled to the surface of substrates constituting the living body-supporting member by integral sintering or bonding, to become the surface of the living body-supporting member. And, by embedding this living body supporting member into the bone, the new bone reproduces and penetrates into pores which constitute the three-dimensional structure, and the bone structure can hold strongly the living body supporting member in the living body by means of its solid structure.

Furthermore, by constituting the dense portion which is the substrate by zirconia or alumina and the porous portion by calcium phosphate-type ceramics, reproduction of the bone to the porous portion can be further promoted, thus the fixation with bone at earlier stage can be made possible.

In addition, it is desirable that said certain depth be in the range of from 100 to 1000 μm . This is because this range is most suitable to promote the reproduction of the new bone into micro pores. If said certain depth becomes larger than 100 μm , the effective diameter of pores at the time of lamination becomes too large to hinder the reproduction of the new bone into micro pores. On the other hand, if it is smaller than 100 μm , the effective diameter of pores becomes too small to cause the similar problems. Furthermore, when said certain depth is not larger than 100 μm , the strength of the porous portion may become weak, thus it is not suitable for the application to the portion where large load is given.

Brief Description of the Drawings

Fig. 1 is a perspective view showing a tape (green sheet) laminated at the time of production of the living body-supporting member in an example of the present invention.

Fig. 2 is a longitudinally sectional view of the living body-supporting member in an example of the present invention.

Fig. 3 is a perspective view of a femur component of an artificial knee as the living body-supporting member in an example of the present invention.

Fig. 4 is a perspective view of an artificial root of tooth as the living body-supporting member in an example of the present invention.

Fig. 5 is a plan view of the porous portion constituting the living body-supporting member in an example of the present invention.

Fig. 6 is a sectional view along the line A-A of Fig. 5.

Fig. 7 is a sectional view along the line B-B of Fig. 5.

Examples

Examples of the present invention will now be described in detail with reference to the accompanying drawings.

(Example 1)

To 100% by weight of alumina powder having an average particle diameter of 0.4 μm were added 0.3% by weight of dispersing material, 8% by weight of organic binder, 0.2% by weight of antifoaming agent, and 25% of water was added thereto to adjust a slip, which was used to prepare a tape having a thickness of 0.3 mm by a doctor blade method. This tape was cut to a desired size, and perforated by punching. There are two types of pore patterns, and one type is such that circular pores having a diameter of 1.0 mm are perforated at 1.5 mm pitches. Another type is that circular pores having a diameter of 2.0 mm are perforated at 3 mm pitches. These two types of tapes T were alternately laminated up to 8 layers so that pores H could be communicated with each other as shown in Fig. 1 to form a porous body. Next, this porous body was bonded to a plate material cut from a rubber press molded body which had the same quality of the material with that of this tape, and dried and fired at a temperature of 1550°C in an oxidizing atmosphere, thus the living body-supporting member P of the present invention which was a two-layer structure comprising a surface layer composed of porous portions 1 and a parent material composed of dense portions as shown in Fig. 2 was obtained.

Fig. 3 shows femur component F of an artificial knee with porous body N bonded thereto prepared by the above-mentioned method.

Furthermore, Fig. 4 shows a ceramic implant D for dental applications with porous body N bonded to a bone-embedded portion prepared by the above-mentioned method.

(Example 2)

To 100% by weight of zirconia powder having an average particle diameter of 0.6 μm were added 0.5% by weight of dispersing material, 10% by weight of organic binder, 0.5% by weight of antifoaming agent, and 25% of water was added thereto to prepare a slip, which was used to prepare a tape having a thickness of 0.5 mm by a doctor blade method. This tape was cut to a desired size, and punched with a mold so that slits of 0.5 mm were made at 1 mm pitches. This tape was alternately laminated up to 8 layers so that slits S were orthogonal to form a porous body. Next, this porous body was bonded to a plate material cut from a zirconia rubber press molded body which had the same quality of the material with that of this tape, and fired at a temperature of 1450°C in an oxidizing atmosphere, thus the living body-supporting member comprising porous portions 1 and dense portions was obtained. Figs. 5 - 7 show the

structure of porous portions 1 of this living body-supporting member.

(Example 3)

To 100% by weight of apatite powder having an average particle diameter of 1 μm were added 1.0% by weight of dispersing material, 5% by weight of organic binder, 0.5% by weight of antifoaming agent, and 20% of water was added thereto to prepare a slip, which was used to prepare a tape having a thickness of 0.5 mm by a doctor blade method. This tape was subjected to punching as in Example 1 and laminated up to 20 layers so that pores could communicate with each other, to obtain a porous body. This porous body was fired at a temperature of 1300°C in an oxidizing atmosphere, thus the living body-supporting member composed of apatite was obtained.

(Example 4)

To 100% by weight of zirconia powder having an average particle diameter of 0.6 μm were added 0.8% by weight of dispersing material, 5% by weight of organic binder, 0.5% by weight of antifoaming agent, and 30% of water was added thereto to prepare a slip, which was used to prepare a thin plate or 40 x 50 x 0.6 mm by a cast molding method. One type is such that this thin plate was subjected to punching to make circular pores having a diameter of 0.5 mm at 1.0 mm pitches. Another type is such that circular pores having a diameter of 0.5 mm were punched at 1.0 mm pitches. These two types of thin plates were alternately laminated up to 8 layers so that pores could communicate with each other to form a porous body. This porous body was bonded to the cast molded body prepared by said slip, dried, and fired at a temperature of 1450 °C in an oxidizing atmosphere.

(Example 5)

To 100% by weight of apatite powder having an average particle diameter of 1 μm were added 1.0% by weight of dispersing material, 5% by weight of organic binder, 0.5% by weight of antifoaming agent, and 20% of water was added thereto to prepare a slip, which was used to prepare a tape having a thickness of 0.5 mm by a doctor blade method. This tape was subjected to punching to make circular pores as in Example 1 and laminated up to 8 layers so that pores could communicate with each other, to obtain a porous body.

Furthermore, a plate material was prepared by a cast molding method, by using an ultra-fine alumina raw material having a temporary particle diameter of 0.1 μm and an average particle diameter of 0.3 μm , whose firing temperature was 1300°C. Said apatite porous body was bonded to this alumina molded body, which was dried and fired at a temperature of 1300°C in an oxidizing atmosphere, thus the living body-supporting member which was an integrally fired two-layer structure compris-

ing a surface layer composed of apatite porous portions 1 and a parent material composed of alumina dense portions.

In addition, the range of the present invention is not limited by these examples, and the thickness of laminated green sheets may be not fixed, and may be optionally changed so far as it does not depart from the object of the present invention. 5

As described above, in porous portions constituting the surface layer of the living body-supporting member of the present invention, by forming multiple pores communicating with each other, while being displaced for every roughly certain depth, the bone reproduces and penetrates densely, thereby the living body-supporting member is coupled with the bone strongly so that there is no risk that it drops out from the supporting portion. Furthermore, by constituting said porous body with ceramics, even if the substrate is composed of ceramics, the substrate and the porous body can be integrally coupled with each other, thereby there is no risk that both of them may be separated. Furthermore, when the sliding face is composed of ceramics, the abrasiveness becomes excellent by the effect of said integral complement. 10 15 20

In addition, in obtaining such living body-supporting member, the present invention applies the multilayer technique of ceramics and also provides a method to perforate multiple pores in the green sheet of ceramic materials, to optionally laminate said green sheets so that pores communicate with each other, and to fire it. According to this method, such an excellent effect can be exerted that the pore shapes of said porous body can be preliminarily designed so that pores communicate with each other while being displaced for every certain depth, and it can be accurately controlled in the production thereof. 25 30 35

Claims

1. A living body-supporting member comprising ceramics constituting artificial bone, artificial joints, artificial root of tooth and the like and giving no harm to a human body, which has a surface layer with multiple pores formed in predetermined locations with regularity. 40 45
2. A living body-supporting member according to claim 1, wherein said multiple pores communicate with other pores for every certain depth of from 100 to 1000 μm . 50
3. A living body-supporting member according to claim 1, wherein at least said surface layer is composed of a calcium phosphate material. 55
4. A preparation process of a living body-supporting member, including steps of perforating multiple pores arranged regularly in a green sheet having a thickness of from 100 to 1000 μm and comprising

ceramic materials giving no harm to a human body, laminating said green sheets in plural numbers in a state that pores are displaced with each other in the vertical direction, and firing it.

FIG. 1

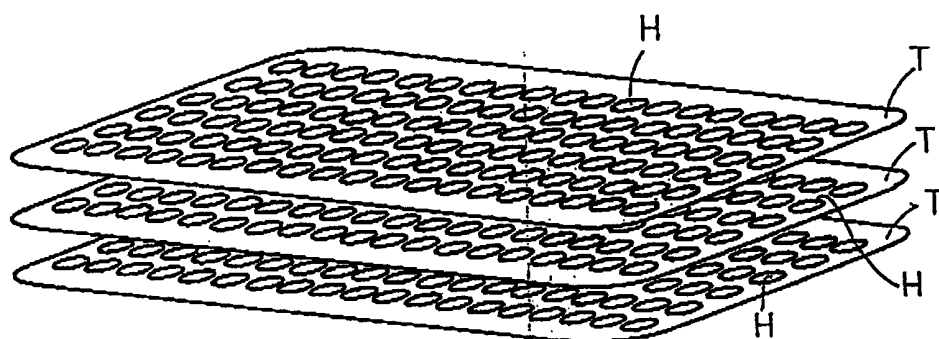


FIG. 2

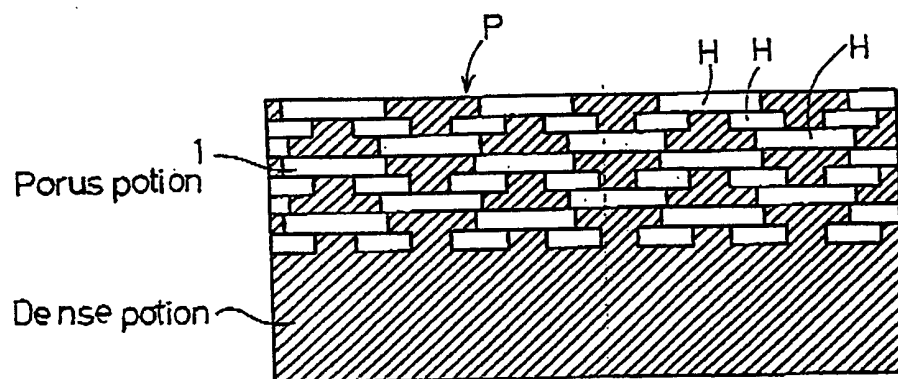


FIG. 3

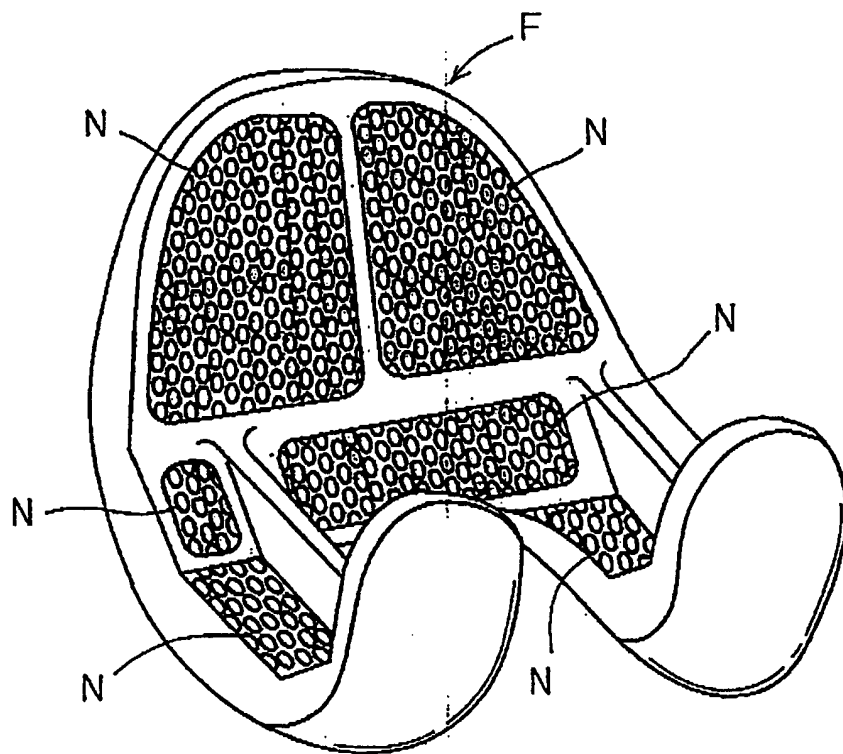


FIG. 4

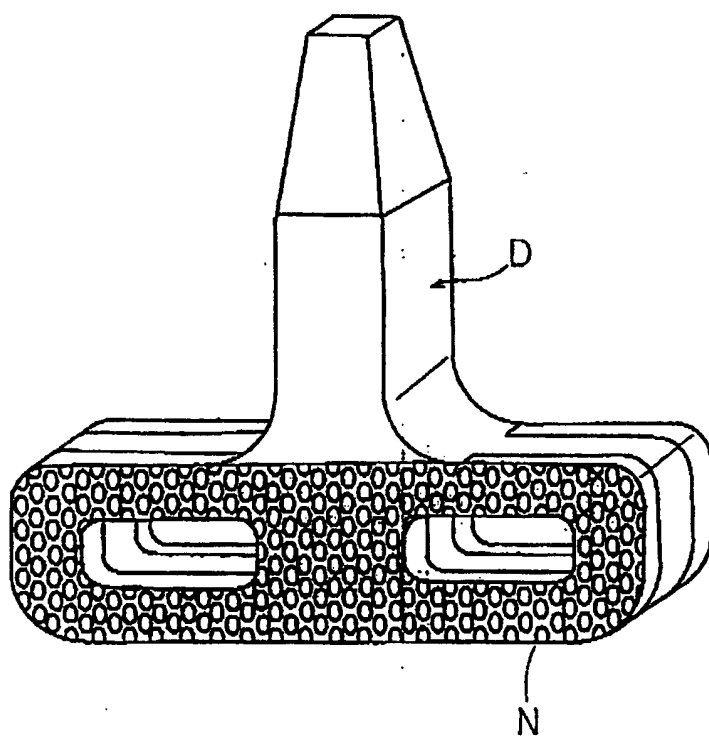


FIG. 5

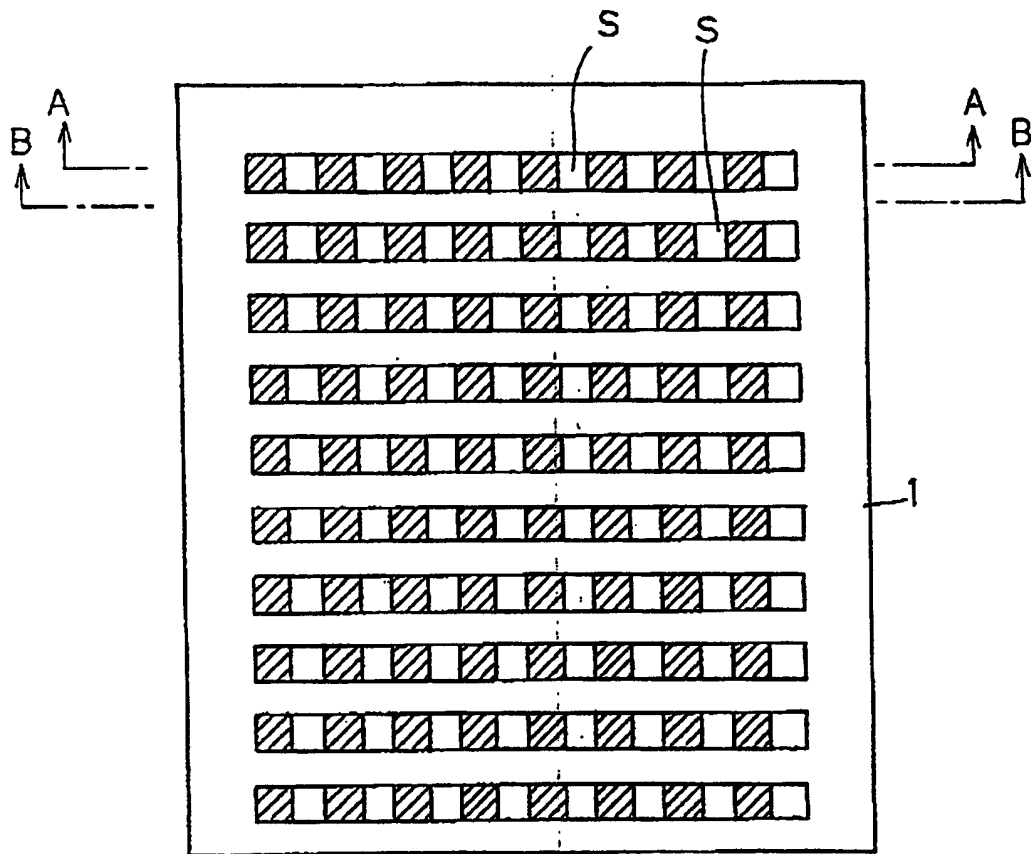


FIG. 6

section A

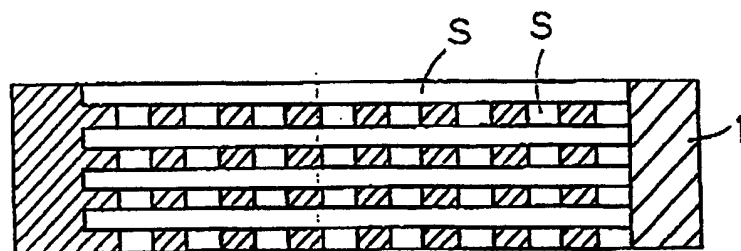
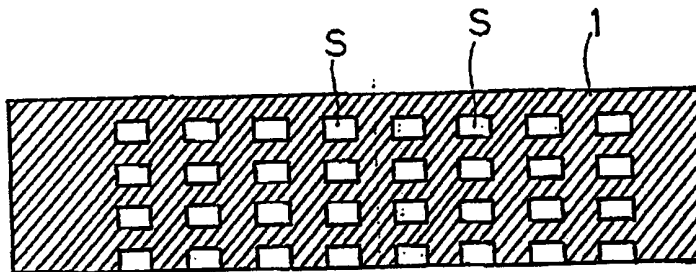


FIG. 7

section B





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 11 9960

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X,P	EP-A-0 647 439 (INTERPORE INTERNATIONAL) * column 8, line 6 - line 20; figures * ---	1-4	A61F2/28 A61F2/30 A61L27/00
X A	WO-A-93 16865 (MARK PATENT) * claims 1,6,10 * ---	1-3 4	
X	EP-A-0 417 034 (GEBR. SULZER AG) * abstract; figures * ---	1,3	
A	US-A-5 296 180 (HAYES ET AL.) * column 14, line 34 - line 52 * ---	1-4	
A	FR-A-2 567 759 (KYOCERA CORP.) * claims 1-6; figures * ---	1-4	
A	EP-A-0 621 018 (KYOCERA CORP.) * abstract; figures * ---	1-4	
A	EP-A-0 602 252 (TORAY INDUSTRIES) * examples * -----	4	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61F A61L
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 26 March 1996	Examiner Villeneuve, J-M
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 01.82 (P04C01)